

Appl. No. : 10/771,845  
Filed : February 4, 2004

## REMARKS

Applicant initially would like to thank Examiner Melissa Ryckman for the courtesies extended Applicant's representatives during the phone interview held on December 9, 2008, summarized above.

By way of summary, Claims 1-7, 10-13, 15, 16, and 48-56 are pending in this application. In the outstanding Office Action of September 12, 2008, Claims 1-7, 10-13, 15, 16 and 48-56 were rejected under 35 U.S.C. §103(a) as unpatentable over Shaw (U.S. 6,080,182). Claims 1, 2, 10, 49, 52, 55 and 56 have been amended.

### **I. Claim Amendments**

In this Amendment, Claims 1, 2, 10, 49, 52, 55 and 56 have been amended to further define the subject matter for which protection is sought and to expedite issuance of a patent. The Applicant respectfully submits that the claims as previously pending are patentably distinguished over the cited references or any combination thereof. However, to expedite prosecution, Applicant has amended the claims in order to clarify the features of Applicant's claimed invention. Applicant reserves the right to pursue the previously unamended claims or claims of broader scope at a later date.

Support for the amendments is provided in Applicant's specification. For example, some of the support for the amendments describing the patent foramen ovale is provided in Applicant's specification at [0105] as published: "The patent foramen ovale 120 includes a septum primum 116 having a surface 126 adjacent the left atrium 104, and a septum secundum 118 having a surface 124 adjacent the right atrium 114. A tunnel or channel 122 is located between the septum primum 116 and septum secundum 118."

### **II. §103(a) Claim Rejection to Shaw et al. (U.S. 6,080,182)**

The Office Action of September 12, 2008 rejects Claims 1-7, 10-13, 15, 16 and 48-56 under 35 U.S.C. §103(a) as unpatentable over Shaw.

The Office Action admits that Shaw "fails to specify the type of heart defect including a patent foramen ovale (PFO)" at page 5. The Office Action merely makes a conclusory statement that "it would have been obvious to one of ordinary skill in the art to use the defect of Shaw with a PFO." Office Action at page 5. Shaw provides no disclosure, teaching or suggestion of how to

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make the significant modifications that would be necessary to modify, reconfigure and redesign the Shaw device to work in a PFO. Moreover, Applicant submits that that one skilled in the art would not find it predictable or have any reasonable expectation of success that that the device of Shaw alone could be used in a PFO tunnel.

While Shaw may disclose a device for use in a hole, Shaw does not even mention a PFO nor any use of its device in the specialized structure of the PFO. The PFO channel does not consist of a simple open circular hole in a membrane. Rather, the PFO channel is formed by overlapping atrial septa. One would not be motivated to place and use the devices of Shaw in a PFO because Shaw's helical wire structure would separate the flaps of the PFO to allow more fluid flow between the atria, frustrating the purpose of the Shaw device.

More particularly, Shaw defines a defect as generally a hole in the wall of a tissue (Shaw, col. 1, ll. 23-29). Shaw never discloses a PFO, nor does Shaw disclose a channel formed by overlapping flaps. It is not obvious that the Shaw device, designed for holes, can be used to close channels comprised of overlapping flaps that have different functional characteristics than those of holes. Applicant respectfully disagrees with the rejection because stating "it would have been obvious to one of ordinary skill in the art to use the defect of Shaw with a PFO" with the teachings of Shaw alone does not lead to predictable results since the Shaw device is not configured to deploy in a PFO and cannot be modified to work in a PFO because the Shaw helical structure would interfere with the closure of the PFO's overlapping flaps.

As disclosed in Applicant's specification, the PFO is different from a general septal defect, which tends to be a through hole in a wall: "In contrast to other septal defects which tend to have a generally longitudinal axis, a patent foramen ovale tends to behave like a flap valve. Accordingly, the axis of the patent foramen ovale tends to be at an angle, and almost parallel to the septal wall." Applicant specification at [0009]. Shaw does not mention any PFO, septum primum, septum secundum, or any flap structure or channel formed between flaps associated with its septal defects. Shaw is directed to block circular holes. Some of the Shaw Figures referenced in the office action include:

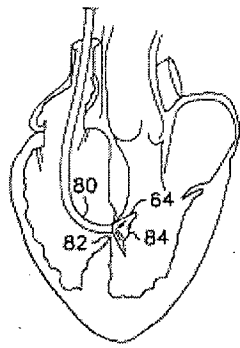


FIG. 7A

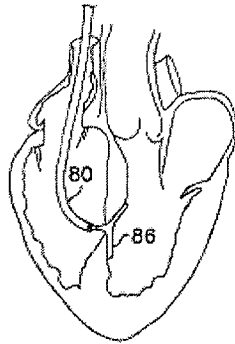


FIG. 7B

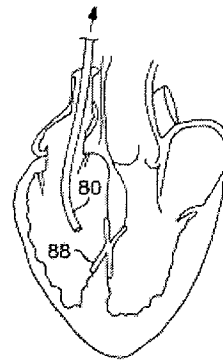


FIG. 7C

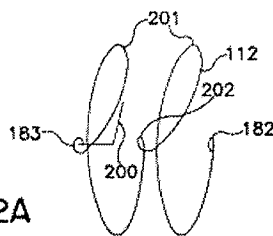


FIG. 32A

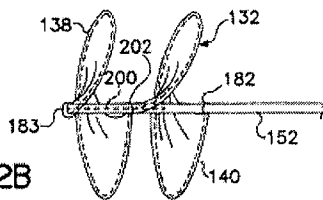


FIG. 32B

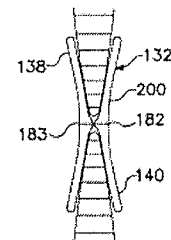


FIG. 32C

The cited Figures clearly show Shaw's device used in simple holes in septa.

Applicant respectfully disagrees with several of the Office Action's characterizations of Shaw. First, Shaw does not "teach a method of closing a patent foramen ovale having a septum primum and a septum secundum (Figs. 7A, 7B)" in Figures 7A, 7B, or anywhere in any of the Shaw reference.

Amended Claim1 recites, in part, "deploying the closure device within the patent foramen ovale such that the second clip-shaped portion is positioned over a tip of the septum primum and the first clip-shaped portion is positioned over a tip of the septum secundum, with the intermediate segment lying in the channel between the overlapping septum primum and the septum secundum." The Office Action characterizes Shaw as having "proximal segment (182), an intermediate segment (202) and a distal segment (183), the proximal and intermediate segments defining a first clip-shaped portion (112) and the intermediate and distal segments defining a second clip-shaped portion (left portion of 201 in Fig. 32A)." Office Action at page 2. However, Shaw fails to disclose, teach or suggest "deploying the closure device within the patent foramen ovale such that the second clip-shaped portion is positioned over a tip of the septum primum and the first clip-shaped portion is positioned over a tip of the septum secundum, with the intermediate segment lying in the channel between the overlapping septum primum and the

septum secundum” as claimed in amended independent Claim 1. Shaw does not disclose, teach or suggest an “intermediate segment lying in the channel between the overlapping septum primum and the septum secundum.”

Claim 1 recites, in part, “wherein the closure device when deployed exerts a force to draw the septum primum and septum secundum together.” Amended Claim 10 recites, in part, “wherein the closure device when deployed exerts a force to draw the septum primum and septum secundum together.” Page 3 of the Office Action argues that the Shaw “closure device when deployed exerts a force to draw the septum primum and septum secundum together (Figs. 7, 32C).” The septa in Figs. 7 and 32C are not overlapping, rather they are positioned one above the other as edges of a hole, as drawn in Shaw’s figures. In this orientation, the clamping force of the Shaw device cannot draw these septa closer together. The Shaw closure device when deployed exerts a force in a direction normal to the plane of the septa. Thus, Shaw’s closure device may squeeze the edge on both sides of a planar hole septal defect, but it does not “draw the septum primum and septum secundum together” as recited in Claims 1 and 10.

Amended Claim 10 recites, in part, a “method of closing a patent foramen ovale having a channel formed between overlapping surfaces of a septum primum and a septum secundum, the septum primum having a proximal surface and a distal surface adjacent the left atrium, the septum secundum having a proximal surface adjacent the right atrium and a distal surface, the channel disposed between the overlapping proximal surface of the septum primum and the distal surface of the septum secundum.” Shaw does not disclose, teach, or suggest a “method of closing a patent foramen ovale having a channel formed between overlapping surfaces of a septum primum and a septum secundum, the septum primum having a proximal surface and a distal surface adjacent the left atrium, the septum secundum having a proximal surface adjacent the right atrium and a distal surface, the channel disposed between the overlapping proximal surface of the septum primum and the distal surface of the septum secundum.” Amended Claim 10 also recites, in part, “deploying the closure device in the channel of the patent foramen ovale, wherein the closure device when deployed includes a first clip-shaped portion positioned around the septum secundum and a second clip-shaped portion positioned around the septum primum.” Shaw does not disclose, teach, or suggest “deploying the closure device in the channel of the patent foramen ovale.”

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The Office Action characterizes Shaw's flexible inner tube 152 as a locking element that is "separate from the proximal segment, intermediate segment and the distal segment." Office Action at page 3. The Office Action indicates that once the flexible inner tube 152 is removed the Shaw "locking element" locks. Claims 49 and 52 recite, in part, "wherein the locking element is provided as a retained part of the closure device after deployment." Since Shaw's locking element (flexible inner tube 152) is removed to lock the Shaw device, it fails to be "a retained part of the closure device after deployment." Claims 55 and 56 recite, in part, "wherein the locking element remains within the patent foramen ovale after deployment." Since Shaw's locking element (flexible inner tube 152) is removed to lock the Shaw device, it fails to remain "within the patent foramen ovale after deployment."

Accordingly, at least independent Claims 1 and 10 and their dependent claims are allowable over Shaw. For at least the foregoing reasons, Applicant respectfully submits that independent Claims 1 and 10 are rendered obvious by Shaw. The remaining rejected claims under Shaw (2-7, 11-13, 15, 16 and 48-56) depend from one of independent Claims 1 and 10 and are allowable for the same reasons set forth above with respect to Claims 1 and 10 in addition to the patentable subject matter contained therein. Accordingly, withdrawal of the §103 rejections based on Shaw regarding Claims 1-7, 10-13, 15, 16 and 48-56 is respectfully requested.

### **III. No Disclaimers or Disavowals**

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, the Applicants are not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. The Applicants reserve the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that the Applicants have made any disclaimers or disavowals of any subject matter supported by the present application.

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#### **IV. Co-Pending Applications of Assignee**

Applicant wishes to draw the Examiner's attention to the following co-pending applications of the present application's assignee.

<b>Serial Number</b>	<b>Title</b>	<b>Filed</b>	<b>Matter Reference</b>
11/607237	TISSUE OPENING OCCLUDER	11/30/2006	EV3.062DV2
11/927448	TISSUE OPENING OCCLUDER	10/29/2007	EV3.062C1
10/419412	SEPTAL DEFECT OCCLUDER	4/21/2003	EV3.058CPC1
10/227773	DEFECT OCCLUDER RELEASE ASSEMBLY AND METHOD	8/26/2002	EV3.059C1
12/110186	RETRIEVABLE SEPTAL DEFECT CLOSURE DEVICE	4/25/2008	EV3.067C1C1
10/972635	PATENT FORAMEN OVALE CLOSURE SYSTEM	10/25/2004	EV3.079A
10/783783	DEVICES AND METHODS FOR CLOSING A PATENT FORAMEN OVALE WITH A COIL-SHAPED CLOSURE DEVICE	2/20/2004	MVMDINC.060A
10/841880	DEVICES AND METHODS FOR CLOSING A PATENT FORAMEN OVALE USING A COUNTERTRACTION ELEMENT	5/7/2004	MVMDINC.068A

#### **V. Conclusion**

Applicant respectfully submits that the claims are in condition for allowance. Furthermore, any remarks in support of patentability of one claim should not be imputed to any other claim, even if similar terminology is used. Any remarks referring to only a portion of a claim should not be understood to base patentability on that portion; rather, patentability must rest on each claim taken as a whole. Applicant respectfully traverses each of the Examiner's rejections and each of the Examiner's assertions regarding what the prior art shows or teaches, even if not expressly discussed herein.

Applicant respectfully requests that a Notice of Allowance be issued at the earliest opportunity. However, if the Examiner has any questions or concerns, the Examiner is invited to telephone Applicant's attorney of record so that extended prosecution of this application may be avoided.

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Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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